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10/802,315	03/17/2004	Jenny Voit	60474-009	4928

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EXAMINER

SHECHTMAN, SEAN P

ART UNIT	PAPER NUMBER
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2125

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/802,315

Applicant(s)

VOIT ET AL.

Examiner

Sean P. Shechtman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 15-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 15-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-10 and 15-24 are presented for examination. Claims 1-10 and 15-24 have been amended. Claims 11-14 and 25-27 have been cancelled.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the a data input for inputting patient data corresponding to a curvature of the patient's spine corresponding to factors independent of the curvature of the spine; selecting a plurality of orthosis models; determining a curvature type of the patient's spine from a predefined number of curvature types on the basis of the patients data; must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

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be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. Objections withdrawn in light of the amendment filed December 19th 2005.

Claim Objections

4. Objections withdrawn in light of the amendment filed December 19th 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-10 and 15-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the patient's spine" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "the patient's spine" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Referring to claim 1, 4, 15, and 18, claims 1 and 15 recite the limitation of inputting a patient's data corresponding to a curvature of the patient's spine and claims 4 and 18, which depend on claims 1 and 15 respectively, recite the limitation of obtaining the patient's data corresponding to factors independent of the curvature of the spine. The examiner respectfully submits that it is not clear how the patient's data can correspond to a curvature of the patient's spine and corresponding to factors independent of the curvature of the spine.

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Claim 1 recites the limitation “the curvature type” in line 7, however, claim 1 recites the limitations of “a curvature type” and “a predefined number of curvature types”, therefore, it is not clear which curvature type is “the curvature type”.

Referring to claim 1, what corresponds to a curvature of the patient’s spine, - inputting, a patient, data?

Claim 2 recites the limitation "said inputting step" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Referring to claims 1 and 15, it is unclear what is done “with a curvature determination device”, - determining a curvature type of the patient’s spine or storing of a predefined number of curvature types in a database?

Referring to claims 1 and 15, it is unclear what is done “on the basis of the patient’s data”, - determining a curvature type of the patient’s spine or storing of a predefined number of curvature types in a database?

Claim 4 recites the limitation "the patient’s data corresponding to factors independent of the curvature of the spine" in lines 1-4. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites the limitation "the patient’s data corresponding to factors independent of the curvature of the spine" in lines 1-4. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 depends on claim 9, and therefore is indefinite.

Claim 6 recites the limitation "the predefined number of orthosis models in the data base" in lines 1-4. There is insufficient antecedent basis for this limitation in the claim.

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Claim 18 recites the limitation "the patient's data corresponding to factors independent of the curvature of the spine" in lines 1-4. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "the patient's data corresponding to factors independent of the curvature of the spine" in lines 1-5. There is insufficient antecedent basis for this limitation in the claim.

Claim 20 recites the limitation "the predefined number of orthosis models" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 24 recites the limitation "the predefined number of curvature types" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim.

Due to the number of 35 USC § 112 rejections, the examiner has provided a number of examples of the claim deficiencies in the above rejections, however, the list of rejections may not be all inclusive. Applicant should refer to these rejections as examples of deficiencies and should make all the necessary corrections to eliminate the 35 USC § 112 problems and place the claims in proper format.

Due to the vagueness and a lack of clear definition of the terminology and phrases used in the specification and claims, the claims have been treated on their merits as best understood by the examiner.

Claim Rejections - 35 USC § 101

6. Rejections withdrawn in light of the amendment filed December 19th 2005.

Claim Rejections - 35 USC § 102

7. Rejections withdrawn in light of the amendment filed December 19th 2005.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-10 and 15-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,850,836 to Steiger et al (hereinafter referred to as Steiger) in view of U.S. Pat. No. 6,463,351 to Clynch (supplied by applicant).

Referring to claims 1, 4, 15, 18, Steiger teaches a method and device for producing an model applicable to the study of bones for a patient comprising:

a data input for inputting patient data, corresponding to a curvature of the patient's spine corresponding to factors independent of the curvature of the spine (Col. 5, lines 38- Col. 6, line 12);

determining a curvature type of the patient's spine from a predefined number of curvature types stored in a database with a curvature determination device on the basis of the patient's data wherein the curvature type is defined by a number of points of deflection of an abstract spine and one or more directions of curvature of the abstract spine (Col. 6, lines 39-53; Col. 7, lines 9-35; Col. 8, lines 1-5; Col. 14, lines 16-24); and

selecting a model applicable to the study of bones from a predefined number of models applicable to the study of bones on the basis of the determined curvature type (Col. 13, lines 44-50).

Referring to claims 2, Steiger teaches the patient's data contain *one or more* elements from the group of: radiographs, photographs of the back, static body dimensions, dynamic body dimensions and age of the patient (Col. 5, lines 38- Col. 6, line 12).

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Referring to claims 3 and 17, Steiger teaches selecting a plurality of models in dependence on the patient's data (Col. 10, lines 51 – Col. 11, line 7).

Referring to claims 5, 6, 10, 19, 20, 21, 24, Steiger teaches modifying the selected model in response to the patient's data corresponding to factors independent of the curvature of the spine, and adding the modified model to the predefined number of models in the database; assigning a new curvature type based on the patients data and adding the new curvature type to the predefined number of curvature types in the data base (Col. 6, lines 39-53; Col. 7, lines 9-35; Col. 8, lines 1-5).

Referring to claim 16, Steiger teaches the database comprises one-valued *or* many-valued allocations or relationships of curvature types to models related to the study of bones, and wherein the model related to the study of bones selection device is suited to select a model related to the study of bones on the basis of these allocations (Col. 6, lines 39-53; Col. 7, lines 9-35).

Referring to claims 1-6, 10, 15-21, 24, Steiger teaches all of the limitation set forth above, however, Adler fails to teach the models are orthosis models.

However, referring to claims 1-10 and 15-24, Clynych teaches analogous art (both in the background of the invention and the invention itself), wherein a system and method adapted for producing many medical devices from models such as, orthotic structures, including those applicable to a patients back (Abstract; Col. 7, lines 13-51), in which the manufacture of such devices from the models makes the devices more widely available to the public at less cost, and furthermore, is very effective in producing custom fitted prosthetic and orthotic devices which are comfortable to wear and provide extensive service (Col. 1, lines 5-49).

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Referring to claims 7-9, 22, 23, Clynch teaches analogous art (both in the background of the invention and the invention itself), comprising producing an orthosis mould according to the selected or modified orthosis model; refinishing the produced orthosis mould; reading in the refinished orthosis mould; and adding an orthosis model according to the read-in orthosis mould to the predefined number of orthoses models (Col. 10, lines 1-35).

Therefore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made to modify the teachings of Steiger with the system and method adapted for producing many medical devices from models such as, orthotic structures, including those applicable to a patients back, as taught by Clynch.

One of ordinary skill in the art would have been motivated to combine these references because Clynch teaches a system and method adapted for producing many medical devices from models such as, orthotic structures, including those applicable to a patients back (Abstract; Col. 7, lines 13-51), in which the manufacture of such devices from the models makes the devices more widely available to the public at less cost, and furthermore, is very effective in producing custom fitted prosthetic and orthotic devices which are comfortable to wear and provide extensive service (Col. 1, lines 5-49).

Response to Arguments

9. Applicant's arguments filed December 19th 2005 have been fully considered but they are not persuasive.

Applicant argues that the amendment overcomes the previous 35 U.S.C. 112 second paragraph rejections. The examiner respectfully disagrees. The limitation of a patient does not provide the proper antecedent basis for the limitation of "the patient's spine". The examiner

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respectfully submits that a spine is not an inherent feature of a patient. For example, a veterinarian might consider an invertebrate (animal without a spine), a patient.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., correlating the curvature of the patient's spine with one of a plurality of curvature types) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

10. All other arguments with respect to claims 1-10 and 15-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean P. Shechtman whose telephone number is (571) 272-3754.

The examiner can normally be reached on 9:30am-6:00pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo P. Picard can be reached on (571) 272-3749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SPS

Sean P. Shechtman

February 23, 2006

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